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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,872	04/02/2002	Jean-Pierre Blareau	33339/242251	8072

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EXAMINER

BRADRIK, THOMAS DALE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,872	<b>Applicant(s)</b> BLAREAU ET AL.	
	<b>Examiner</b> Thomas D. Bradrick	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/26/01</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-11 are pending. Claims 6-10 are being examined on the merits. Claims 1-5 and 11 are withdrawn from examination as being drawn to non-elected inventions. Election was made with traverse in the reply filed December 16, 2005. Applicant's claim to foreign priority is acknowledged. A certified copy of the foreign priority document has been made of record.

### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 6-9, in the reply filed on December 16, 2005 is acknowledged. The traversal is on the ground(s) that the method of Group I, claims 1-5, is specially adapted for the production of the product of Group II, and that the invention has a special technical feature not taught in the reference (Mutai *et al.*, U.S. Patent 4,187,321) cited in the restriction requirement filed November 29, 2005, namely the particular strain of *B. breve* claimed. This is not found to be persuasive. Claim 1 of the instant application is drawn to a method comprising keeping a milk substrate in contact with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by *Bifidobacterium*. Claim 1, upon which claim 6 depends, does not require the strain to which claim 5 is drawn. Furthermore, it has not been established by evidence that the strain of claim 5 is different from the strains disclosed in Mutai *et al.* Assigning a strain a different identification number does not necessarily make the strain different. Mutai *et al.* disclose inoculating a 16% whole fat milk medium with *B. longum* and *B. bifidum* for cultivation under aerobic conditions (Example 1,

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bottom of col. 4 and top of col. 5). Mutai *et al.* therefore clearly anticipate the method of claim 1 of the instant application. As a consequence, no special technical feature unites the inventions of Groups II and I, and the restriction requirement is deemed to be proper. With respect to applicant's assertion that the method of Group I is specially adapted for the production of the product of Group II, this argument is found to be unclear. Restriction of applications filed under 35 U.S.C. 371 is based solely on unity of invention, or lack thereof, between inventive groups belonging to only one of the statutory combinations of categories listed in the restriction requirement filed November 29, 2005. With respect to product-by-process claims such as those of Group II, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production [MPEP 2113].

Finally, the examiner sincerely regrets having overlooked claim 10 of the preliminary amendment filed December 26, 2001, and claim 11, which was subsequently added March 7, 2002. Claim 10, drawn to the milk food of amended claim 9, will be examined on the merits along with claims 6-9. The addition of claim 11, drawn to *B. breve* strain I-2219, is acknowledged. Claim 11 will not be examined on the merits, however, as it is not a member of elected Group II.

The restriction requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The disclosure is objected to because of the following informalities: the sentence "It is possible to add to the milk-based medium the ingredients necessary for producing

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the product ready for consumption which it is desired to obtain" (p. 3, ll. 36-38) is extremely awkward, if not unclear.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the details of the method being referred to in claim 6. Claim 6 is improperly dependent on a nonelected claim and thereby fails to recite the details of the method being referred to therein. For examination purposes only, claim 6 will be read as being drawn to a milk product obtained by a method comprising contacting a milk substrate with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by *Bifidobacterium*.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mutai *et al.* [A].

Claim 6 is drawn to a milk product obtained by contacting a milk substrate with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by said bacterium.

Mutai *et al.* [A] disclose milk products obtained by cultivation with either *B. longum* and *B. bifidum* (Example 1) or *B. bifidum* and *B. breve* (Example 2) under aerobic conditions (bottom of col. 4 and top of col. 5). It is noted that the bacterial count is still low after 17 hours (Table 1), which would indicate a pH of between 6 and 7. This would inherently result in the production of an immunostimulant because of the pH.

Claims 6-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yang *et al.* (U.S. Patent 5,711,977) [B].

Claim 6 is drawn to a milk product obtained by contacting a milk substrate with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by *Bifidobacterium*. Claim 7 further specifies that the milk product of claim 6 have a pH of between 6 and 7. Claim 8 is drawn to a milk food obtained from the product of claim 7, which is further specified in claim 9 to have a pH of between 6 and 7.5.

Yang *et al.* [B] disclose 12% reduced skim milk inoculated with different strains of *Bifidobacteria* and cultured under aerobic conditions, several of which (*B. bifidum* ATTC 29521, *B. breve* ATTC 15700 and *B. longum* ATTC 55813) maintained a pH of greater than 6 after 22 hours (Example 6 and Table V). This pH would inherently result in the milk product being an immunostimulant.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang *et al.* [B].

Claim 6 is drawn to a milk product obtained by contacting a milk substrate with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by *Bifidobacterium*. Claim 7 further specifies that the milk product of claim 6 have a pH of between 6 and 7. Claim 8 is drawn to a milk food obtained from the product of claim 7, which is further specified to have a pH of between 6 and 7.5 (claim 9), and between 6.5 and 6.9 (claim 10).

Yang *et al.* [B] disclose 12% reduced skim milk inoculated with different strains of *Bifidobacteria* and cultured under aerobic conditions, several of which (*B. bifidum* ATTC 29521, *B. breve* ATTC 15700 and *B. longum* ATTC 55813) maintained a pH of greater

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than 6 after 22 hours (Example 6 and Table V). Yang *et al.* [B] also disclose that *B. longum* ATTC 55813 has an optimal growth pH of 6.5 to 7.5 (col. 8, l. 4). Yang *et al.* [B] do not, however, disclose the production of a milk food with a pH of between 6.5 and 6.9. It would nevertheless have been obvious to one of ordinary skill in the art at the time the invention was made that the final pH of the milk food could be increased from about 6.03 to between 6.5 and 6.9 by titration with a suitable base in order to obtain, with a reasonable expectation of success, a milk food with a pH of between 6.5 and 6.9 and obtained from a milk product obtained by contacting a milk substrate with a *Bifidobacterium* culture under conditions that are unfavorable to fermentation by *Bifidobacterium*. This would have the obvious advantage of producing a food with a near-neutral pH to satisfy persons who do not like a substantial acid taste, and *Bifidobacteria* that are still viable. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, claims 6-10 are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is 571-272-8139. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached at 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
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J.D.B.



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